



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,818	05/23/2001	Daniel M. Gorman	DX01170K	8990
28008	7590	12/05/2003	EXAMINER	
DNAX RESEARCH, INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/863,818

Applicant(s)

ORMAN, DANIEL M.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's amendment filed on 26 September 2003 is acknowledged and entered. Following the amendment, claim 26 is canceled, claims 21-25 are amended, and the new claim 27 is added.

Currently, claims 21-25 and 27 are pending and under consideration.

The declaration under 37 CFR 1.132 filed on 26 September 2003 is acknowledged, and it is insufficient to overcome the following rejection of claims 21-25 based upon lack of utility and enablement under 35 U.S.C. 101 and 112, first paragraph, for the reasons addressed under "Objections and Rejections under 35 U.S.C. §101 and §112" below.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 26 are moot as the applicant has canceled the claim.

The prior art rejections made in the last Office Action, paper No. 12, are withdrawn in view of applicant's amendment.

The rejection of claims 22-25 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendments.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-25 remain rejected, and the new claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility, for the reasons of record set forth in the last Office Action, paper No. 12, mailed on 27 March 2003, at pages 2-5.

Applicants argument, filed on 26 September 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-7 of the response, the applicant argues that the totality of the record includes not only the homology data, but also data on helminth challenge, DCRS9 expression, and additional data filed in the declaration regarding the expression and the ligand of DCRS9. Applicants further argue that the specification asserts that the present invention is involved in innate immunity, the cytokine receptor like proteins will result in *modulation* of innate immunity response. In addition, applicants indicate in the declaration that IL-71 (or IL-17C) is the ligand for DCRS9 (items 6 and 7), that IL-71 increases in response to helminth challenge (item 8), and that DCRS9 is at least a marker for innate immunity (item 9). Applicants argument and the declaration have been fully considered, but they are not persuasive for the following reasons.

With respect to the transient elevation of DCRS9 expression upon helminth challenge, it is not clear what the biological significance of that is, and what specific and substantial, or well-established utility is associated with the activity, as helminth challenge may also alter the expression of other molecules. Such a change in DCRS9 expression upon helminth challenge, at the most, is an interesting invitation for further research and experimentation, which, however, is part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

With respect to the expression data of DCRS9, mere expression is not indicative of involvement in innate immunity. The person of skilled in the art would not accept applicants assertion as being any more than speculation without substantial further research. As such, the expression pattern itself does not confer any meaningful use to the DCRS9, and therefore, cannot be used to support a specific and substantial utility.

With respect to the post filing date reference indicating that IL-71 (or IL-17C) is the ligand for DCRS9, and stimulates an increase in neutrophils in lung, it is irrelevant because the specification *never discloses* that stimulation of DCRS9 could result in an increase in neutrophils. Additionally, the specification does not disclose any possible ligand for DCRS9,

Art Unit: 1646

nor the possibility that DCRS9 may be a member of IL-17 receptor family. A post filing date reference cannot be used to support what is *not disclosed* in the original specification filed.

With respect to the assertion that the cytokine receptor like proteins will result in modulation of innate immunity response, the term “modulation” can be interpreted as either stimulation or inhibition, which are mutually exclusive, indicating that a specific, substantial and credible utility was not defined for the proteins as of the filing date of the priority applications. Such a statement of all options does not constitute an assertion of a specific and substantial utility, but rather demonstrates a “guess” rather than assertion of utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 remain rejected, and the new claim 27 is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the last Office Action, paper No. 12, at page 5.

Applicants argument, filed on 26 September 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that applicant has submitted rebuttal arguments, a declaration, and published articles establishing that the present invention has a credible, specific and substantial utility. This argument is not persuasive for reasons above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1646

Claim 22 remains indefinite for the recitation of “the biding composition ... that is” as the biding composition is not equal to an antibody. “Wherein said biding site is” is suggested.

Claim 24 remains indefinite because it is unclear what “a source of ...” is meant, i.e., is it a cell, a protein, or a catalog? As such, the metes and bounds of the claim cannot be unambiguously determined.

Conclusion:

No claim is allowed.

Art Unit: 1646

Advisory Information:

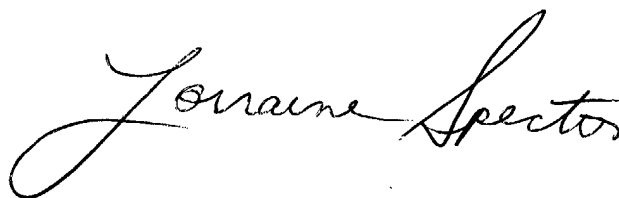
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/20/03